

### REMARKS

Claims 1-3, 6-15, 17-22, 24-28, 30 - 36 and 54 - 73 were pending at the time of the last Office Action (Final Rejection). Claims 2, 19 and 54 - 72 remained withdrawn from consideration as being drawn to non-elected subject matter.

The following claims are currently being amended or canceled:

- (a) Pending claims 6-15, 17, 21, 22, 24, 27, 28 and 31 are amended.
- (b) Claims 2, 3, 19, 20 and 55 and are being canceled herein.
- (c) Withdrawn claims 59-63, 65 and 72 are also amended to bring them into correspondence with the amended active claims.

As to the withdrawn method claims, Applicant refers to the first Office Action on the merits in this case, dated December 4, 2002, in which the Office indicated that the then-existing method claims (corresponding to present claims 54 and 55-72) would be rejoined upon indication of patentable subject matter in the composition claims. These method claims have been amended to render their scope commensurate with the scope of the amended active claims. The Action of December, 2002, acknowledged that allowance of virus or nucleic acid products would result in allowability of withdrawn Groups that were directed to corresponding methods and noted that, in accordance with MPEP § 821.04 and *In re Ochiai*, rejoinder of process claims that are commensurate in scope with allowed product claims will occur following finding that product claims are allowable. Applicant has been mindful to amend the method claims during examination to maintain (a) dependency from product claims and/or (b) inclusion of all limitations of product claims as they were amended. In view of the expected allowance of the product claims, Applicants respectfully request such rejoinder of the process claims (claims 54 and 56-72).

The last Office Action indicated that claims 1, 18 and 73 were allowable, while the remaining claims were rejected under 35 U.S.C. § 112, first paragraph. All other § 112 rejections and prior art rejections were withdrawn.

Careful consideration has been given to the grounds for rejection and the following amendments and remarks are offered in response. All the amendments are supported by the original claims and the specification throughout. No new matter is added by these amendments. Entry of this paper, reconsideration and allowance of the remaining active claims, and rejoinder of the withdrawn claims are respectfully requested.

**I. Withdrawal of Earlier Rejections**

Applicants acknowledge and thank the Examiner for withdrawing of the remaining prior rejections and acceptance of Applicants amendments and arguments with respect to the “non-coxsackievirus” language.

**II. “Second” Rejection for Lack of Adequate Written Description**

Claims 3, 6-15, 17, 20-22, 24-28, 30-36 and 76-78 (namely, all claims that read on the CB4-P virus) were rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office continues to assert that CB4-P is required to practice the claimed invention as a “necessary limitation for the success of the invention as stated in the claims.” As indicated in the Action, as a “required element” it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. An alternate way to satisfy this requirement if the “required element” is not so obtainable or available is by a deposit of coxsackievirus CB4-P under 37 CFR § 1.802 in a recognized deposit facility.

The Office asserted that one cannot practice the claimed invention without the “specifically named” CB4-P coxsackievirus “strain.” The specification was said to “provide a method for obtaining a virus “like CB4-P”, but the Office maintained that the specification does not provide a repeatable method for obtaining the CB4-P without some kind of “access” to the CB4-P. The Office indicated its belief that this virus was not “readily available” material so that deposit of CB4-P would satisfy the enablement requirement. Among other alternatives, the Office Action suggested that if the Applicant wished to claim a “class” of viruses that have the same properties and characteristics as CB4-P, that the laboratory designation “CB4-P” be dropped in favor of some identifying characteristics of the virus

**Applicants’ Response**

After consideration of the options, including those proposed by the Office, Applicant has decided to remove all references to CB4-P in the claims and to make all the claims that depended from prior claim 3 (that included this strain designation), now depend from allowable claim 1 which is directed to CB4 virions with the recited limitations. The same was done with claims that

depended from claim 20, which now depend from allowable claim 18. All additional dependent claims are free of any reference to CB4-P.

Such amendments were proposed to, and discussed with, Examiner Chen during the above-noted phone interview. The undersigned was given to understand that such amendments should overcome the remaining § 112 rejection and that allowance would follow their formal submission.

### **III. Conclusion**


In conclusion, it is respectfully requested that the above amendments, remarks and requests be considered and entered. Applicant respectfully submits that their amendments and remarks have overcome all the pending grounds for rejection and that all the present claims are in condition for allowance. It would further be proper to rejoin claims 54 and 56-72 at this time. Applicants respectfully request early notice of such favorable actions.

**Examiner Chen is respectfully requested to contact the undersigned at (202) 628-5197 (or at the email address [slivnat@browdyneimark.com](mailto:slivnat@browdyneimark.com)) with any final questions or comments, or with proposed Examiner's amendments if such are deemed necessary to bring the claims into final allowable form.**

Respectfully submitted,

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